

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION.

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 32

UNITED STATES PATENT AND TRADEMARK OFFICE

MAILED

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

PAT. & T.M. OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte GEORGE J. MURAKAWA, R. BRUCE WALLACE,
JOHN A. ZAIA, and JOHN J. ROSSI

Appeal No. 93-4018
Application No. 07/402,450¹

ON BRIEF

Before WILLIAM F. SMITH, JOHN D. SMITH, and GRON, Administrative Patent Judges.

WILLIAM F. SMITH, Administrative Patent Judge.

REMAND TO THE EXAMINER

We remand this application to the examiner for consideration of the following issues.

¹ Application for patent filed September 1, 1989.

According to applicants (specification, page 1), the application is a continuation-in-part of (1) 07/355,296, filed May 22, 1989, (2) 07/143,045, filed January 12, 1988, and (3) 07/148,959 filed January 27, 1988. (1) and (2) are each a continuation-in-part of 06/941,379, filed December 15, 1986.

I.

The Examiner's Answer contains a provisional rejection of claims 18 through 25 and 31 through 33 under 35 U.S.C. § 102(e) over application 07/180,740.² The provisional § 102(e) rejection was not previously made in any Office action and therefore constituted a new ground of rejection, although it was not labeled as such.³ Accordingly, appellants have not been provided an opportunity to respond to this rejection.

Upon return of this application, the examiner is to reconsider the provisional rejection under § 102(e) based upon application 07/180,740.⁴ If that application is no longer pending, the examiner should ascertain whether it has been refiled under 35 U.S.C. § 120. If an anticipation issue remains,

² The examiner included claims 26 through 30 in this rejection even though they had been cancelled in Paper No. 10, filed December 4, 1991.

³ Appellants appear to be unaware that this new ground of rejection was made in the answer since the reply brief filed May 7, 1993, which was denied entry, does not acknowledge or respond to the provisional rejection.

⁴ The propriety of such a provisional rejection was addressed in Ex parte Bartfeld, 16 USPQ2d 1714, 1716 (Bd. Pat. App. & Int. 1990) aff'd on other grounds, In re Bartfeld, 925 F.2d 1450, 17 USPQ2d 1885 (Fed. Cir. 1991) where the board noted that an important function of provisional § 102(e) rejections is to "put [an applicant] on notice at the earliest possible time of the possible prior art relationship between copending application."

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the provisional rejection should of course be maintained. If it is maintained, however, the examiner should provide appellants with an appropriate opportunity to respond. If the provisional rejection is not maintained, the examiner should explain clearly why it has been overcome.

II.

The Examiner's Answer contains a second new ground of rejection to which appellants were not permitted to respond. In the final Office action mailed March 19, 1992, claims 18 through 30 were provisionally rejected for obviousness-type double patenting over claims 24 through 53 of application 07/180,740 (Paper No. 13, page 6). In the Examiner's Answer, this provisional rejection was applied to claims 18 through 25 and 31 through 33 and the basis of the rejection was switched to claims 57, 58 and 60 of the 07/180,740 (Paper No. 24, page 5). The switch in the basis of this provisional rejection constituted a new ground of rejection to which appellants should have been given an opportunity to respond.

In addition, the Examiner's Answer does not adequately explain the provisional obviousness-type double patenting rejection. First, the Examiner's Answer contains no explanation

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for the change in the group of claims to which this ground of rejection is applied. Second, the Examiner's Answer contains an inadequate explanation of the relationship between the subject matter of the provisionally rejected claims and the claims of application 07/180,740. The Examiner states only that "both inventions [i.e., that of instant claims 18 through 25 and 31 through 33 and that of claims 57, 58 and 60 of application 07/180,740] are directed to detect an RNA virus via PCR methodology with primers and probes of conserved transcript sequences that are known in the prior art." Examiner's Answer, page 5. This statement also appears in the final Office Action (page 6), where the provisional rejection was over claims 24 through 53 of application 07/180,740. The examiner acknowledges that claims 24 through 53 of application 07/180,740 "have been canceled and amended by the new claims [57, 58, and 60]" (Examiner's Answer, page 8), yet maintains the provisional rejection without any explanation of why the replacement and amendment of the previously problematic claims in application 07/180,740 was ineffective in overcoming the provisional rejection.

Upon return of this application, the examiner is to reconsider the provisional obviousness-type double patenting

rejection. If the provisional rejection is maintained, the examiner should provide appellants with the required opportunity to respond to it. If it is not maintained, the examiner should clearly explain why it has been overcome.

III.

The amendments to claim 18 which were submitted December 1, 1992, and which were entered by the examiner, introduce several sources of apparent ambiguity and indefiniteness into claim 18, and by dependency into all of the claims on appeal. First, part (iv) of claim 18 recites hybridizing an amplified product to a probe and "denaturing resulting hybridization product." Part (v) recites hybridizing "the product of step (iv)" with another probe. It is unclear whether the hybridization of step (v) is intended to be carried out with the "hybridization product" recited in step (iv) or with the product that results from carrying out the recited denaturation step on the "hybridization product."

Second, part (vi) recites "determining . . . whether said reference sequences hybridized with said reference sequence." No previous step recites a step of hybridizing the reference sequence to itself. Also, part (vi) is grammatically confusing.

Third, the results recited to be indicative of false negative data are confusing. Lines 26-28 of claim 18 specify that the "first probe" is homologous to the target sequence, and lines 37-39 recite that "false negative data [are] indicated by failure of either of said first and second probes to hybridize to the sample sequence or to the reference sequence." The wording of the claim implies that false negative data are indicated if either of the probes fails to hybridize to either of the (target or reference) sequences; e.g., by failure of the target probe to hybridize to the reference sequence. But the record indicates that this is not the intended meaning. See, e.g., the chart on page 2 of the Appeal Brief: false negative data are indicated only when the target probe fails to hybridize to the target sequence and when the reference probe fails to hybridize to the reference sequence, but not when either one separately fails to hybridize to its complementary sequence. The chart does not indicate what effect on the assay result would be indicated by failure of each probe to hybridize to the other probe's complementary sequence. The inconsistencies between the claim wording and the assay actually described in the specification causes confusion when interpreting the scope and content of the subject matter claimed.

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Finally, the claim contains several apparent typographical errors. These include at least lines 28-29: "said reference sequence[,] denaturing"; line 29: "denaturing resulting [sic, the resulting] hybridization product"; line 34: "sequence are"; lines 34-36: "hybridized with said first probe whether [sic, and whether] said reference sequences hybridized."

Upon return of the application, the examiner should review all pending claims for compliance with the definiteness requirement of 35 U.S.C. § 112, second paragraph. As set forth in In re Zletz, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989):

An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process.

IV.

Several prior art issues also require further attention from the examiner. First is the issue of the effective filing date for each of the claims on appeal. There is no indication in the record that the examiner has considered whether any claim(s) is(are) entitled to the benefit of the earlier filing date of any of the purported parent applications under 35 U.S.C. § 120. We

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note in this regard that the relationship of the parent cases with each other and with the application on appeal is unclear from the specification and the data which appears on the face of the administrative file. The specification states (page 1, lines 3-9) that the application on appeal is

a continuation-in-part of each of application Serial No. 355,296 filed May 22, 1989, (which is a continuation-in-part of application Serial No. 941,379, filed December 15, 1986), application Serial No. 143,045 filed January 12, 1988 (which is a continuation-in-part of application Serial No. 941,379), and application Serial No. 148,959 filed January 27, 1988 (emphasis added).

The face of the file, on the other hand, indicates that the application on appeal is a CIP (continuation-in-part) of 07/355,296, which is a CIP of 06/941,379 and a CIP of 07/143,045, which is a CIP of 07/148,959. The application relationship on the face of the file differs from that in specification in that: (1) the file face indicates that 07/355,296 is a CIP of 07/143,045, while the specification indicates that the application on appeal is a CIP of 07/143,045, and (2) the file face indicates that 07/143,045 is a CIP of (later-filed) 07/148,959, while the specification indicates that the application on appeal is a CIP of 07/148,959.

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Neither appellants nor the examiner have addressed this problem or attempted to reconcile the conflicting statements. However, even that would not have cured the problem since both the specification and the face of the file are wrong since application 07/355,296 is a file-wrapper continuation, not a continuation-in-part, of application 06/941,379. Upon return of the application, the examiner should first ascertain the correct relationship of the purported parent applications and this application. Then the examiner should make sure that the face of the file and the specification recite the correct information.

Subsequently, the examiner should determine the effective filing date of each claim. See In re van Langenhoven, 458 F.2d 132, 136-37, 173 USPQ 426, 429 (CCPA 1972) where the court stated that "subject matter which is first disclosed in a continuation-in-part application is not entitled to the filing date of the parent application" and "[a]s to given claimed subject matter, only one effective date is applicable." After fixing the filing date of each claim, the examiner should reevaluate the prior art since it is not clear which possible filing date served as the basis for the prior art search.

Turning to the merits of the prior art rejections, the examiner's position as understood is that it would have been

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obvious to use a positive control during PCR amplification of viral RNA because positive controls were well known to people skilled in the art at the time. It is apparent from the claim language, however, that the claimed process requires a specific positive control reaction: simultaneous amplification of two distinct sequences (target and reference) during the PCR reaction.

No mention of positive controls was made in any statement of the obviousness rejections before the Examiner's Answer. See, e.g., the final Office Action, page 5 ("it would have been obvious to one of ordinary skill in the art at the time of the instant invention to apply the PCR technique of Mullis et al. to HIV amplification and detection") and page 6 ("as applied above, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to apply the PCR technique of Mullis et al. to HMCV [sic, HCMV] amplification and detection").

In the Examiner's Answer, the examiner amplifies on the conclusions of obviousness recited in the Office actions, stating on page 4:

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to apply the PCR technique of Mullis et al. to HIV amplification and

detection Even though, that Mullis et al. teach simultaneous amplification of more than one sequence at a time at column 10, lines 47-57. The use of an internal standard or control with a measurement or detection technique has been known since quantitative analysis was first practiced. In view of this, one of ordinary skill in the art would have found it prima facie obvious to use a second sequence of RNA to be co-amplified as an internal control with the reasonable expectation, if not certainty, of distinguishing false positive and false negative results.

The examiner does not refer to any of the cited references to support the statement that positive controls were notoriously well known in the art. But even assuming arguendo that (1) positive controls in general were well known and (2) it would have been obvious to use a positive control in any diagnostic reaction, it is apparent that any number of possible reactions could be run to provide a positive control for a PCR reaction. For example, a separate reaction mixture could be "spiked" with a known amount of the viral RNA being assayed for and then subjected to the same PCR reaction as the test sample. The examiner's statement of the rejection begs the question of why it would have been obvious to run the particular positive control described in the claims; i.e., why would it have been obvious to modify Mullis as required to arrive at the claimed process?

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On return of this application, the examiner should reconsider the basis of the obviousness rejection in light of these comments and in light of other references, if any, found to be prior art during determination of the effective filing date of the claims. If the obviousness rejection is maintained over the current references or modified, the examiner should restate the obviousness rejection to indicate clearly what teachings from the prior art would have made the claimed process as a whole obvious. If the obviousness rejection is withdrawn, the examiner should indicate why the positive control reaction recited in the claims is unobvious over positive control reactions the examiner has asserted are well known in the art.

V.

Finally, there is a question regarding the circumstances of the filing of the application. The cover sheet of the initial application submission (September 1, 1989) indicates that no drawings were filed at that time even though the specification as originally filed referred to Figures 1 1A and 1B at page 12. An amendment was filed December 5, 1991 (Paper No. 12), stating that Figures 1, 1A, and 1B were inadvertently omitted from the

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original filing, and requesting deletion of the drawing descriptions from the specification.

The Manual of Patent Examining Procedure (Sixth Edition, Rev.1, Sept. 1995) (MPEP) provides that:

Applications filed without all figures of drawing described in the specification are not given a filing date since they are "prima facie" incomplete. The filing date is the date on which the omitted figures are filed. . . . If any applicant believes that omitted figures of an application are not necessary for an understanding of the subject matter sought to be patented, applicant may petition to have the application accepted without the omitted figures. Any such petition must be accompanied by the petition fee (37 CFR 1.17(h)) and an amendment cancelling from the specification all references to the omitted figures Also, if the oath or declaration for the application was filed prior to the date of the amendment and petition, the amendment must be accompanied by a supplemental declaration by the applicant stating that the invention is adequately disclosed in, and a desire to rely on, the application as thus amended for purposes of an original disclosure and filing date."

MPEP § 608.02.

Thus, the MPEP sets out four requirements that must be met for an application filed without its drawings to receive a filing date: 1) a petition, 2) the petition fee, 3) cancellation of references to the drawings, and 4) a supplemental declaration. Of these requirements, only the requirement of an amendment

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canceling references to the drawings has been met. Until the requirements of a petition, petition fee, and supplemental declaration are met, the application is prima facie incomplete and therefore cannot be accorded a filing date.

On return of this application, the examiner should notify appellants of the steps they must take to complete the application.

The application, by virtue of its "special" status, requires immediate action. See MPEP § 708.01(d). It is important that the Board of Patent Appeals and Interferences be informed promptly of any action affecting the appeal.

REMANDED

William F. Smith

WILLIAM F. SMITH)
Administrative Patent Judge)

John D. Smith

JOHN D. SMITH)
Administrative Patent Judge) BOARD OF PATENT

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